**Public Health IRB**

**Annual Event Summary Form**

Principal Investigator:

Study Title:

IRB#:

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| 1. Briefly summarize the reportable, unexpected problem events that have occurred since initial review or the last continuing review. (Report forms of these events must have been submitted to the PH IRB in accordance with policy - [www.healthoregon.org/irb](http://www.healthoregon.org/irb)): |

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| 2. Was either the protocol or consent form changed in response to these reports? Explain: | Yes  No |

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| 1. Briefly summarize any unreportable events (events that are not unexpected problems) that have occurred since the last continuing review: | | | |
| **Date of Event** | **Description of Event** | **Severity of Event**  (Mild, Moderate, Severe) | **Relation to the Study** (possibly, probably, definitely or not related) |
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| 4. Did any of the events summarized in Q3 alter risks to past or current research participants? If yes, explain: | Yes  No |

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| 5. Based on your analysis of these events, do you believe the problem should be identified in the consent form as a possible risk?  If no, why not:  If yes, provide suggested language: | Yes  No |

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| 6. Based on your analysis of these events, should currently enrolled subjects or subjects who have completed participation in the study be notified? Explain: | Yes  No |

Investigator Signature:                      Date: